

REMARKS

Claims 1-13 are pending in the application.

Election/Restriction

The Examiner has required restriction of the invention under 35 U.S.C. § 121 to one of the following groups:

Group I: Claims 1-3, 5 are drawn to a method of identifying a compound that modulates hepatocyte growth, plasma cell differentiation, and T cell subset activity in a non-human XBP-1 deficient animal. Classified in class 800, subclass 21.

Group II: Claims 1, 4, and 5 drawn to a method of identifying a compound that modulates cell physiological activity in cultivated hepatocytes or plasma cells, or a subset of T cells deficient in XBP-1. Classified in class 435, subclass 4.

Group III: Claims 6-8 are drawn to a method for inhibiting cellular activities (hepatocytes, plasma cells or T cells) comprising contacting said cells with a modulator of XBP-1 activity *in vivo*, wherein the modulator is an antisense oligonucleotide. Classified in class 514, subclass 4.

Group IV: Claims 6, 7, 9 are drawn to a method for inhibiting cellular activities (hepatocytes, plasma cells or T cells) comprising contacting said cells with a modulator of XBP-1 activity *in vivo*, wherein the modulator is an intracellular antibody. Classified in class 424, subclass 130.1.

Group V: Claims 6, 10, 11 are drawn to a method for stimulating cellular activities (hepatocytes, plasma cells or T cells) comprising contacting said cells with a modulator or XBP-1 activity *in vivo*, wherein the modulator is an expression vector encoding XBP-1. Classified in class 514, subclass 44.

Group VI: Claims 6, 10-13 are drawn to a method for modulating cellular activities (hepatocytes, plasma cells or T cells) comprising contacting said cells with a modulator of XBP-1 activity *in vitro*. Classified in class 435, subclass 375.

In addition the Examiner has required the election of a single species of one cell type, *i.e.*, hepatocyte, plasma cell, or T cell subset.

The Examiner is of the opinion that the inventions are distinct, each from the other because

groups I-VI are drawn to different methods, each drawn to different means of identifying compounds or modulating cell activity. Different inventive processes use different starting materials (isolated cells or animals), different test criteria to measure the effects of testing compounds, have different method steps, different modes of operation, and have distinct technical considerations.

The Examiner is also of the opinion that the

application contains claims directed to patentably distinct species of the claimed invention: Inventions I-VI are directed to methods using different types of cells in screening or modulating the activity of different cell types.

In order to be considered responsive to the instant Office Action, Applicants' hereby elect Group II (claims 1, 4, and 5) directed to a method of identifying a compound that modulates cell physiological activity in *cultivated* hepatocytes or plasma cells, or a subset of T cells deficient in *XBP-1*, **with traverse**. Applicants further elect the species of hepatocytes, without traverse. Applicants traverse the restriction requirement for the following reasons.

Applicants respectfully submit that the instant Restriction Requirement is improper for the following reasons. Applicants have presented an allowable generic claim, claim 1 which embraces the method of identifying a compound that modulates hepatocyte growth, plasma cell differentiation, and T cell subset activity regardless of whether the cells are present in a non-human XBP-1 deficient animal or removed from the non-human XBP-1 deficient animal. Claim 1 is drawn to a method of identifying a compound that modulates hepatocyte growth or plasma cell differentiation or T cell subset activity by contacting hepatocytes or B cells or T cells deficient in XBP-1 with a test compound and determining the effect of the test compound on the growth of the hepatocytes or differentiation of the B cells into plasma cells or Th2 cytokine production by the T cells. The test compound is identified as a modulator of hepatocyte growth or plasma cell differentiation or T cell subset activity based on the ability of the test compound

to modulate the growth of the hepatocytes or differentiation of the B cells or Th2 cytokine production by the T cells deficient in XBP-1.

It is Applicants' position that given the presence of claim 1, which embraces methods of identifying a compound that modulates hepatocyte growth or plasma cell differentiation or T cell subset activity in a non-human XBP-1-deficient animal and in a cell deficient in XBP-1 *in vitro*, a restriction under 35 U.S.C. §121 is improper. Applicants submit that while a species election may be proper for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, an election under 35 U.S.C. §121 is improper since the claims are linked by an allowable generic linking claim.

If a species election is required, Applicants further provisionally elect methods performed in a cell deficient in XBP-1 *in vitro* for search purposes only. It is Applicant's understanding that under 35 U.S.C. §121, an election of a single species for prosecution on the merits is required, to which the claims will be restricted if no generic claim is finally held allowable. Applicants submit that at least claim 1 is generic. Applicants further understand that upon allowance of a generic claim, they will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141 *et seq.*


Furthermore, with regard to the unelected groups, Applicants submit that Groups III, IV, V, and VI should be reformed as a single group containing claims 6-13. Claim 6 is an allowable generic claim which embraces the species of inhibiting and stimulating hepatocyte growth or plasma cell differentiation or T cell subset activity. Claim 6 also embraces the species of modulating hepatocyte growth or plasma cell differentiation or T cell subset activity *in vivo* and *ex vivo*. Thus, claim 6 is generic to the groups set forth by the Examiner for the reasons set forth above for claim 1.

CONCLUSION

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

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Respectfully submitted,

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